K131304

MAY 2 9 2014

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Submitter's Identification:**

Aashish Shah
Vice President of Quality & Operations
Sentio, LLC
50461 W Pontiac Trail
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Date Summary Prepared: April 29th, 2014

2. **Name of the Device:**

Trade or Proprietary Name:	Sentio MMG®
Classification Name:	Neurosurgical Nerve Locator
Device Class:	Class II
Classification:	21 CFR §874.1820
Product Code:	PDQ

3. **Common or Usual Name:**

Nerve Mapping and Avoidance System, Intraoperative Mechanomyographic (MMG) Monitor/Stimulator, Nerve Locator/Stimulator

4. **Predicate Device Information:**

The subject device Sentio MMG® is substantially equivalent to the following predicate device:

K100992 NeuralMAS™, Innovative Surgical Solutions, LLC d/b/a Sentio, LLC, Wixom, Michigan

5. Device Description:

The Sentio MMG® system is a multichannel intraoperative monitor for use during surgeries in which a motor nerve is at risk. The Sentio MMG® system records mechanomyographic (MMG) signals from muscles innervated by the affected nerve, which may originate from operator applied electrical stimulus or from direct or indirect mechanical stimulus occurring during the course of surgery. The monitor will assist early nerve identification by providing the surgeon with a tool to help locate and identify the particular nerve at risk to minimize trauma by alerting the surgeon when a particular nerve has been activated.

The Sentio MMG® system consists of a reusable Control Unit comprised of a touch-screen PC and Patient Module, a reusable Sensor Connector Module and an assortment of disposable conductive probes, stimulators, sensors, electrodes and electrode leads.

6. Intended Use:

This device is intended for use in surgical procedures to assist in locating and mapping motor nerves through the use of mechanomyographic (MMG) signals and electrical stimulus of nerves. This device is indicated for locating and identifying spinal nerve roots and peripheral motor nerves originating from spinal levels C3-T1 and L2-S2.

7. Comparison to Predicate Devices:

The subject device has indications for use which are the same as the predicate device, K100992, is composed of the same materials as the predicate commercially marketed device, has the same or equivalent design features as the predicate device, is substantially equivalent in its method of use, incorporates the same fundamental scientific technology and has functional characteristics which are the same or equivalent to those of the predicate device. Due to the equivalency of indications for use, materials of composition, design features, method of use, scientific technology and functional characteristics, the device raises no new safety or effectiveness issues.

A comparison of the technological characteristics to the predicate device is provided below:

Table 1: Overview & Indications

Subject Device: Sentio MMG® #K131304	Predicate Device: ISS NeuralMAS #K100992
System Overview Uses low level electrical current to stimulate nerves sufficient to produce a detectable mechanical signal in contracting muscle using skin-surface mounted mechanomyographic (MMG) sensors.	**System Overview** Uses low level electrical current to stimulate nerves sufficient to produce a detectable mechanical signal in contracting muscle using skin-surface mounted mechanomyographic (MMG) sensors.

Table 2: Physical Attributes

Attribute	Sentio MMG® #K131304	ISS NeuralMAS #K100992
Control Module: PC/Display		
Type:	Touchscreen	Touchscreen
Number of Channels:	10	10
Channel Enable/Disable Controls:	Touchscreen controlled	Touchscreen controlled
Event Threshold Control and Display:	Touchscreen controlled	Touchscreen controlled
Stimulator		
Type Constant:	Electrical Current (mA)	Electrical Current (mA)
Range: Control:	1-15 mA	1-15 mA
Waveform:	Digitally controlled	Digitally controlled
Pulse Duration:	Monophasic, square pulse	Monophasic, square pulse
	100µs	100µs

Rate:	2Hz	2Hz
Stimulus Probe:	Monopolar	Monopolar
Activation:	Touch screen or hand switch	Touch screen or hand switch
Monitoring Sensor		
Function:	Mechanomyographic (MMG)	Mechanomyographic (MMG)
Type: Attachment	Electromechanical	Electromechanical
Site: Attachment	Skin surface	Skin surface
Mode:	Adhesive	Adhesive

8. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

A comparative performance evaluation was conducted to assess statistical agreement between the subject device and the predicate. Results for positive, negative, and overall percent agreement have established that 1) the principle functions of the Sentio MMG® system are effective, such that spinal nerve status and location may be ascertained and monitored, and 2) the data processed by the subject device following surgical use correlate well with those acquired by the predicate device.

9. **Discussion of Clinical Tests Performed:**

Not Applicable

10. **Conclusions:**

The conclusions drawn from our non-clinical testing (to include our market data evaluation) of the subject device demonstrates that the subject device is as safe, as effective and performs better than the legally marketed predicate device. Any noted differences between the devices are minor and do not raise new issues of safety and effectiveness. The subject device is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2014

Innovative Surgical Solutions, LLC
Mr. Aashish Shah
Vice President Quality & Operations
21520 Bridge Street
Southfield, MI 48033

Re: K131304
Trade/Device Name: Sentio MMG
Regulation Number: 21 CFR 874.1820
Regulation Name: Neurosurgical Nerve Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: April 29, 2014
Received: April 30, 2014

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131304

Device Name
Sentio MMG

Indications for Use *(Describe)*
This device is intended for use in surgical procedures to assist in locating and mapping motor nerves through the use of mechanomyographic (MMG) signals and electrical stimulus of nerves. This device is indicated for locating and identifying spinal nerve roots and peripheral motor nerves originating from spinal levels C3-T1 and L2-S2.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.05.29 22:30:24 -04'00'

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